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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/243,030	02/03/1999	MICHAEL GERARD TOVEY	23164-1001-D	1869
1444 7590 04/04/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER ANDERSON, JAMES D	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/243,030

Applicant(s)

TOVEY, MICHAEL GERARD

Examiner

James D. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-57 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/853,870.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 11/3/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 22-57 are currently pending and are the subject of this Office Action. Claims 22-24, 36-40, 46-48 and 52 are presently amended.

Response to Amendment

The prosecution history of the instant case is complicated. A thorough review of the record indicates that there has been much confusion regarding the limitation "oromucosal contact" and exactly what this limitation does and does not include. For example, previous Examiners (Mr. Goldberg and Ms. Cook) have interpreted this limitation to include both oral administration and nasal administration. Applicants have argued that oromucosal contact does not include oral administration (Arguments filed 1/25/2002, page 9) or nasal administration (Arguments filed 10/3/2005, page 4). The present Examiner now refers to Applicant's disclosure to aid in the interpretation of "oromucosal contact". At page 7, lines 7-10, Applicants disclose that compositions for oromucosal administration may be provided as "a solution, tablet, lozenge, gel, syrup, paste, or controlled release oromucosal delivery system". Applicants further disclose

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that interferon may be administered “by any means which provides contact of the IFN with the oromucosal cavity of the recipient” (page 12, lines 11-12). This may be achieved “with liquids, solids, or aerosols, as well as nasal drops or sprays” (*id.* at lines 12-15). Taken together, the limitation “oromucosal contact” and the definitions provided in the disclosure support

Applicant’s arguments that the claims do not read on oral administration (wherein a composition is swallowed and enters the GI tract) or nasal administration (wherein the composition enters the lungs). It is the present Examiner’s position that the limitation “oromucosal contact” is limited to such treatments wherein a composition remains in contact with the oromucosa. As such, this limitation excludes oral and nasal administration.

Further confusion has arisen with respect to the dose of interferon being administered as well as limitations in the claims wherein “the interferon does not enter the bloodstream” (*e.g.*, claim 37). Applicants provide evidence that the interferon found in blood and serum following oromucosal contact is biologically inactive (page 34, lines 1-3). It is the present Examiner’s position that “oromucosal contact” as recited in the instant claims must necessarily result in biologically inactive interferon entering the bloodstream. As such, any prior art reference that contemplates oromucosal administration will inherently read on this limitation. Further, limitations in the claims wherein the amount of interferon administered is greater than, for example, 20×10^6 IU for a 70 kg human only apply to a 70 kg human and do not define the dose for humans who do not weigh 70 kg. As such, the claims contemplate any dose of interferon for a human not weighing 70 kg.

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The present Examiner has carefully gone through the prosecution history and Applicant's claim amendments in response to previous Office Actions. There are several instances where claim amendments introduced new matter into the claims (see below).

Claim Objections

Claim 36 is objected to because of the following informalities: the word "ormuscosal" is misspelled in line 9. The correct spelling is ---oromucosal--- as found elsewhere in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36 and 38-51 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

In the amendments filed 12/8/2000, Applicants submitted new claim 36, which recited the limitation, "...and provided that when the viral infection is a rhinoviral infection, the interferon is not administered through the mouth by multiple or continuous doses." In response to the Advisory Action mailed 1/5/2001, in which Examiner Goldberg indicated that claim 36

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would introduce new matter into the claims, Applicants subsequently amended claim 36 (papers filed 2/8/2001) to recite the limitation, "...and provided that when the viral infection is a rhinoviral infection, the interferon is administered in a single dose or is administered intranasally by multiple or continuous doses." However, Applicants subsequently reintroduced the limitation, "...and provided that when the viral infection is a rhinoviral infection, the interferon is not administered in a multiple or continuous dose or is administered intranasally by multiple or continuous dose" in the response filed 1/25/2002. Claim 36 presently recites the limitation, "...and provided that when the viral infection is a rhinoviral infection, the interferon is not administered through the mouth in a multiple or continuous dose." Thus, the claim now recites subject matter that was originally found to be new matter (per Advisory Action mailed 1/5/2001).

It is the present Examiner's position that the originally filed specification does not provide support for any of the above recited claim limitations, which attempt to specifically exclude (or specifically include) specific administration regimens (routes, schedules, etc.) for rhinoviral infections. Rhinovirus is disclosed at page 10, line 25. Nasal administration is disclosed at page 12, line 15. Administration by multiple or continuous dosages is described at page 12, lines 21-25. Administration in a single dose which is not a multiple or continuous dose is described at page 12, line 20. However, these individual teachings in the specification do not provide support for the instantly claimed limitation. Nowhere do Applicants specifically contemplate not treating a rhinoviral infection via administration of interferon through the mouth in a multiple or continuous dose. As such, claim limitations reciting positive or negative limitations with respect to rhinoviral infections specifically are not supported by the

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specification. The originally filed disclosure contemplates treating any viral infection, including rhinoviral infection, by the disclosed administration routes and schedules.

Claims 22-57 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for biologically active interferon not entering the bloodstream, does not reasonably provide enablement for interferon not entering the bloodstream. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

The instant claims are drawn to methods of administering interferons via oromucosal contact. Claims 36, 37 and 52 recite the limitation wherein the interferon does not enter the bloodstream. However, Applicants have shown that detectable levels of radiolabelled Hu IFN- α 1-8 were found in both whole blood and serum of animals following oromucosal administration. While the radioactive material was biologically inactive, it is clear that radiolabelled interferon was found in the blood.

Amending the claims to recite that "biologically active interferon" does not enter the bloodstream would overcome this rejection.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 22-57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, independent claims 36, 37 and 52 recite dose limitations where in the amount of interferon recited is “for a 70 kg human”. These dose limitations only apply to a 70 kg human. As such, it is not clear at what dose the interferon will be administered to humans not weighing 70 kg.

Claims 22 and 23 recite the limitation “the effective amount” in line 2 of each respective claim. There is insufficient antecedent basis for this limitation in the claim. Claims 22 and 23 depend from claim 37, which recites “an amount” of interferon is administered. Nowhere does claim 37 recite an “effective” amount.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-35 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eby, III (U.S. Patent No. 5,286,748; Issued Feb. 15, 1994) (prior art of record).

The instant claims recite methods for treating viral infections comprising administering greater than 30×10^6 IU (claims 22-35 and 37) of an interferon for a 70 kg human via oromucosal contact (claim 37). Dependent claims further limit claim 37 to specific administration regimens, doses and viral infections. With respect to the dose of interferon being administered, Examiner notes that the limitations “greater than 30×10^6 IU” of an interferon “for

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a 70 kg human” only apply to a 70 kg human. Thus, the claims read on any dose being administered for any human not weighing 70 kg.

Eby discloses a method of treating the common cold by administering medicaments “to and into the oral tissues” (Abstract). The invention specifically claims the utility of application of medicinal agents to the oral and oropharyngeal mucous membranes rather than the nose or by ingestion (*id.*). The application of antiviral agents to the oral mucosa through the incorporation of said antiviral agents within a slow release lozenge has the potential to allow the medicament to absorb into the lymphatic system or otherwise circulate into the nasal tissue and the locus of the infection (col. 4, lines 9-15). Interferons are disclosed at column 5, line 44. An example of an interferon composition can comprise 1 to 20 million IU (col. 8, lines 20-22). Claim 5 of the Eby patent specifically claims treatment of the common cold comprising “often repeated administration” of an antirhinoviral medication (including interferon) that releases the medicament in the oral cavity to facilitate absorption of the medicament into the oral and oral pharyngeal membranes.

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed methods would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The differences between the claimed methods and those disclosed in Eby lie in the amount of interferon administered as well as the specific dosing regimens contemplated. However, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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In the instant case, Eby discloses the general conditions of methods for treating rhinoviral infections via oromucosal contact of antiviral agents. As such, the instantly claimed administration regimens, doses and specific species of interferons are not inventive over Eby.

Further, it would have been obvious, given the general conditions disclosed in Eby, that higher doses of interferon could be used effectively in the methods disclosed therein. In addition, the skilled artisan would have been imbued with at least a reasonable expectation that other dosing regimens of interferon could be used to treat viral infections while maintaining efficacy. Applicants have provided no evidence that the administration regimens (*i.e.* multiple doses vs. single dose, administration through the mouth vs. nasal administration, etc.) are critical to the claimed methods and unobvious over the prior art. Finally, as noted *supra*, the instantly claimed limitation wherein the amount of interferon is greater than 30×10^6 IU of an interferon for a 70 kg human only applies to a 70 kg human. As such, the claims read on any amount of interferon being administered to humans not weighing 70 kg.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson, Ph.D.
Patent Examiner
AU 1614

March 26, 2007



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